UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., et al.,

Plaintiffs,

v.

INTUITIVE SURGICAL, INC.,

Defendant.

Case No. 21-cv-03496-AMO

ORDER RE MOTIONS IN LIMINE

Re: Dkt. Nos. 290, 292, 293, 296, 296, 301, 302, 303

The Court held a pretrial conference in this antitrust case on November 25, 2024. The Court heard argument on the parties' motions in limine at the conference. Having carefully considered the arguments advanced at the hearing, together with the parties' papers and the relevant legal authority, the Court rules on the motions in limine as follows.

I. LEGAL STANDARD

"A motion in limine is a procedural mechanism [that is used] to limit in advance" of trial the scope of "testimony or evidence in a particular area" that will be permitted at trial. *United States v. Heller*, 551 F.3d 1108, 1111-12 (9th Cir. 2009). Though not explicitly authorized by the Federal Rules of Evidence (FRE), the practice of ruling in limine on evidentiary issues is based on the "district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "[I]n limine rulings are not binding on the trial judge, and the judge may always change [their] mind during the course of a trial." *Ohler v. United States*, 529 U.S. 753, 758 n.3 (2000) (emphasis removed). "A motion in limine is not the proper vehicle for seeking a dispositive ruling on a claim, particularly after the deadline for filing such motions has passed." *Hana Financial, Inc. v. Hana Bank*, 735 F.3d 1158, 1162 n.4 (9th Cir. 2013).

II. SURGICAL INSTRUMENT SERVICE COMPANY, INC.'S MOTIONS IN LIMINE

Plaintiff Surgical Instrument Service Company, Inc. ("SIS") filed five motions in limine. The Court granted stipulations resolving SIS's motions in limine #2 and #3. *See* ECF 308, ECF 309.

At the conference, the Court denied SIS's motion in limine #4 subject to revival at trial if Defendant fails to lay a sufficient foundation for lay witness testimony.

The Court discusses SIS's remaining motions in limine, #1 and #5, together because the Court's reasoning regarding introduction of evidence of the Food and Drug Administration ("FDA") regulatory framework bears on each motion. In its motion in limine #1, SIS moves to exclude all testimony, documentary evidence, and argument related to (1) the FDA's Section 510(k) regulatory framework and procedures for clearance of medical devices for commercial marketing, (2) the meaning, scope and application of the regulatory term "remanufacturing," (3) whether SIS or other third parties' EndoWrist activities constitute "remanufacturing" or require 510(k) approval; and (4) the meaning, scope, application and effect of Intuitive's announcement on its website that buying FDA-cleared remanufactured EndoWrists does not violate its contracts. In its motion in limine #5, SIS moves to exclude all testimony, documentary evidence, and argument related to (1) the FDA's regulatory framework and procedures for clearance of medical devices for commercial marketing [same as in #1] , (2) Intuitive's FDA 510(k) clearance of EndoWrists [similar to #1], (3) the contention that Intuitive's FDA 510(k) clearance of EndoWrists requires adherence to Intuitive use limits; (4) the contention that Intuitive's FDA 510(k) clearance of EndoWrists is evidence that those use limits ensure or relate to patient safety; and (5) the contention that Intuitive's FDA 510(k) clearance of EndoWrists is evidence of the actual number of times an EndoWrist can be used from an engineering/failure perspective.

Courts regularly exclude evidence regarding the FDA's 510(k) clearance process based on a pair of interlocking concerns. First, Section 510(k) clearance involves an inquiry into a new device's equivalence with an earlier-approved medical device, not, as Intuitive contends here, an inquiry into the safety of the new product. *See Meditronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (explaining, "the § 510(k) process is focused on *equivalence*, not safety" (emphasis in original)).

Second, and because Section 510(k) clearance does not address issues of safety, any probative value of the evidence related to the regulatory framework and a plaintiff's failure to obtain such clearance is greatly outweighed "by the danger of, among other things, confusing the issues, misleading the jury, and wasting time." *Kaiser v. Johnson & Johnson*, No. 2:17-CV-114-PPS, 2018 WL 1358407, at *4 (N.D. Ind. Mar. 16, 2018) (denying motion in limine to admit FDA evidence and granting motion in limine to exclude FDA 510(k) evidence), aff'd, 947 F.3d 996 (7th Cir. 2020).

Both concerns merit exclusion here. The same risk of confusing the jury applies here and warrants exclusion of the regulatory evidence. Intuitive aims to present evidence of the Section 510(k) process to demonstrate a lack of safety for SIS serviced instruments, but Section 510(k) simply is not oriented towards ensuring safety of medical devices. *See Meditronic*, 518 U.S. at 493. Although Section 510(k) clearance is clearly relevant in the context of this case and how it has been litigated so far, the regulatory framework cannot be invoked to demonstrate deficient product safety. The voluminous record arising from SIS's failure to obtain Section 510(k) clearance presents a substantial risk of confusing matters for the jury because the complex record related to regulatory compliance could lead jurors "to erroneously conclude that regulatory compliance proved safety." *In re C. R. Bard, Inc.*, 81 F.3d 913, 922 (4th Cir. 2016); *see also id.* at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Intuitive can and should present evidence concerning repaired EndoWrists's safety, including through other available evidence, such as any testing data, engineering data, and appropriate expert testimony. Intuitive cannot, however, invite the jury to conclude that SIS's failure to obtain 510(k) clearance demonstrates that SIS's services were unsafe.

Intuitive contends that the cases cited by SIS are unhelpful here because they considered 510(k) clearance in the product liability context. *See* Intuitive Opp. to MIL #1 at 5 n.4. But the reasoning underpinning 510(k) clearance exclusion in the products liability context applies equally here. Indeed, Intuitive aims to proffer 510(k) clearance evidence for the same purpose discounted in the product liability cases – as a proxy or indication of product safety. *Compare* Intuitive Opp.

to MIL #1 at 1-3 *with Carter v. Johnson & Johnson*, No. 220CV01232KJDVCF, 2022 WL 4700549, at *2 (D. Nev. Sept. 29, 2022) (finding that a "mini-trial" on Section 510(k) evidence " 'could easily inflate the perceived importance of compliance and distract the jury from the central question before it,' whether the defendants' product was unreasonably dangerous." (citation omitted)). And here, just as in the product liability context, evidence of the 510k clearance regime is ancillary to the gravamen of the claims at issue. *See id.* There, the regulatory scheme did not resolve the issue of whether the challenged products were poorly or unsafely designed; here, the regulatory scheme does not resolve the issue of whether Intuitive engaged in anticompetitive conduct. And here, perhaps to an even greater extent than in the product liability cases, evidence regarding the regulatory scheme and either side's compliance threatens to itself create a "mini-trial" that would greatly distract the jury. The Court accordingly **GRANTS** the portions of SIS's motion in limine #1 to exclude all testimony, documentary evidence, and argument related to (1) the FDA's Section 510(k) regulatory framework and procedures for clearance of medical devices for commercial marketing, (2) the meaning, scope and application of the regulatory term "remanufacturing," and (3) whether SIS or other third parties' EndoWrist activities constitute "remanufacturing" or require 510(k) approval.

The fourth part of SIS's motion of limine #1 merits separate discussion as it relates to Intuitive's announcement on its website that buying FDA-cleared remanufactured EndoWrists does not violate its contracts. *See* Rosa Decl. ¶ 45 (ECF 137-2) (quoting in part from Intuitive's March 2023 website announcement, "Intuitive will not void its service contract with, cease doing business with, or consider it a breach of contract by a customer in the United States who chooses to purchase remanufactured instruments that have been remanufactured by a third party pursuant to and in compliance with a 510(k) clearance or equivalent granted by the FDA."). The announcement cannot be presented to the jury without contextualizing its reference to 510(k) clearance, which would require presenting additional evidence that would turn into a sideshow

likely to distract and confuse the jury.[1] The Court therefore **GRANTS** SIS's motion in limine to exclude the exclude all testimony, documentary evidence, and argument related to the meaning, scope, application and effect of Intuitive's announcement on its website that buying FDA-cleared remanufactured EndoWrists does not violate its contracts.[2]

This same reasoning generally applies to SIS's motion in limine #5. Accordingly, the Court **GRANTS** SIS's motion in limine #5 to exclude all testimony, documentary evidence, and argument related to (1) the FDA's regulatory framework and procedures for clearance of medical devices for commercial marketing [same as in #1], (2) Intuitive's FDA 510(k) clearance of EndoWrists [similar to #1], (3) the contention that Intuitive's FDA 510(k) clearance of EndoWrists requires adherence to Intuitive use limits; (4) the contention that Intuitive's FDA 510(k) clearance of EndoWrists is evidence that those use limits ensure or relate to patient safety; and (5) the contention that Intuitive's FDA 510(k) clearance of EndoWrists is evidence of the actual number of times an EndoWrist can be used from an engineering/failure perspective. Intuitive may not present evidence that the use counters/use limits were required pursuant to the FDA's regulatory approval, but Intuitive may present argument and evidence that the use counters/use limits constituted a safety feature that warranted protection. Intuitive argues that it must still be permitted to advance the use limits and other safety concerns as part of its pro-competitive rationale. Intuitive may do so, though not by validating those safety concerns through the 510(k) scheme because 510(k) clearance does not address product safety.

Through its oppositions to SIS's motions in limine #1 and #5, Intuitive aims to relitigate the role the regulatory framework played in SIS's market participation. This issue was already

[1] The Court further finds that the announcement demonstrates an attempt to privately enforce the Food, Drug and Cosmetic Act ("FDCA"), which the Court earlier determined is prohibited as a matter of law. *See* Order re Cross MSJs (ECF 204) at 12-14. Intuitive may not rely on its announcement, an improper attempt to privately enforce the FDCA by requiring compliance with a regulatory scheme unenforced by the FDA, to excuse its business conduct.

[2] The Court additionally finds that admission of this website announcement, made in the period following the close of fact discovery and prior to summary judgment briefing in this case, would prove inequitable in light of the Court's grant of Intuitive's motion to exclude most fact evidence arising following the close of fact discovery in November 2022. *See* discussion of Intuitive's motion in limine #4, below.

resolved at summary judgment. The Court denied Intuitive's motion, which asserted that SIS could not establish antitrust causation because the regulatory framework interfered with SIS's market participation rather than Intuitive's allegedly anticompetitive conduct. *See* Order re Cross MSJs (ECF 204) at 16 (discussing *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165-66 (3d Cir. 2017); *Modesto Irrigation Dist. v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156, 1170 (N.D. Cal. 2004)). The Court stated that neither party could aim to enforce the FDCA through this case. *See* Order re Cross MSJs (ECF 204) at 12-14. Yet Intuitive seems to do exactly that – to establish that SIS failed to obtain 510(k) clearance as if it was required.

In sum, though Intuitive argues that SIS distorts the record by trying to avoid discussing FDA clearance in a case about medical devices and safety, it is Intuitive that distorts the gravamen of the case. This antitrust case is about allegedly anticompetitive conduct. And, again, Intuitive mischaracterizes the import of 510(k) clearance, which the Supreme Court has recognized is not concerned with safety. For these reasons, among the others discussed above, the Court **GRANTS** SIS's motions in limine #1 and #5.

III. INTUITIVE SURGICAL, INC.'S MOTIONS IN LIMINE

Intuitive Surgical filed five motions in limine. The Court granted a stipulation resolving Intuitive's motion in limine #5. *See* ECF 326. The Court additionally granted a stipulated briefing schedule regarding an evidentiary proffer related to Intuitive's motion in limine #1, and the Court therefore does not reach that motion in this order. The Court takes up the remaining three motions.

A. Intuitive's Motion in Limine #2

Intuitive moves for an order prohibiting: (1) SIS from either introducing into evidence or referencing the Deutsche Bank analyst reports dated January 27, 2020 and February 20, 2020 (the "Reports"); and (2) SIS's experts from incorporating the opinions of the Reports' authors as part of those experts' own opinions.

Intuitive argues that the reports themselves constitute inadmissible hearsay, including multiple layers of hearsay in their reference to unidentified "surgeons and supply chain executives." *See* Fed. R. Evid. 801, 802, 803. Moreover, the reports constitute improper lay and

expert testimony where they opine on, among other things, hospital demand for third-party repaired EndoWrists, the safety risk posed by those repairs, and whether FDA approval is required for such repairs. *See* Fed. R. Evid. 701 & 702. SIS opposes Intuitive's requested exclusion.

The Court **DENIES** Intuitive's motion to exclude the Reports because they may prove admissible for a non-hearsay purpose. Assuming proper foundation, SIS may proffer the Reports to show that Intuitive was aware of the competitive threat posed by third-party activities refurbishing EndoWrist instruments discussed in the Reports. The Court otherwise finds the hearsay exceptions identified by SIS inapplicable to the Reports, and no party may proffer the Reports for the truth of their contents. *See* Fed. R. Evid. 803(3), 803(6), 803(17).

To the second part of this motion, Intuitive improperly attacks SIS's experts' reliance on the Deutsche Bank reports because experts need not rely on admissible evidence in forming their opinions. The Court finds that this portion of Intuitive's motion simply amounts to a collateral attack on the Court's *Daubert* rulings on Lamb and Bero, and the Court declines to limit the experts' testimony in this way.

B. Intuitive's Motion in Limine #3

Intuitive moves for an order: (1) prohibiting Plaintiff SIS from introducing evidence that Intuitive has been sued by other parties in other cases or referring to other litigations and settlements involving Intuitive, including the litigation and settlement in *Restore Robotics LLC v. Intuitive Surgical, Inc.*, No. 5:19-cv-00055 (N.D. Fla.), the litigation and settlement in *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, No. 8:20-cv-02274 (M.D. Fla.), the still-pending litigation in *Restore Robotics Repairs LLC v. Intuitive Surgical, Inc.*, No. 3:24-cv-00444 (N.D. Fla.), and the still-pending putative class action litigation against Intuitive in the matter of *In re: Da Vinci Surgical Robot Antitrust Litigation*, No. 3:21-cv-03825-AMO (N.D. Cal.); and (2) requiring the parties to redact any references to other litigation or settlements in any documents or deposition designations.

The Court **GRANTS** Intuitive's motion in limine #3 because Intuitive's litigation history will likely prove more prejudicial than probative. The prohibitions against introducing evidence

or making reference to other litigations and settlements apply to both SIS and Intuitive with equal force.

C. Intuitive's Motion in Limine #4

Intuitive moves for an order prohibiting SIS from offering any evidence or argument about the time period following November 10, 2022 (the close of fact discovery in this case), other than SIS's recently produced financial records and responses to requests for admission. Intuitive sought to take discovery of facts and events occurring after November 2022. The Court denied Intuitive's motion to compel such discovery, with two narrow exceptions, requiring SIS to: (1) produce updated financial records, and (2) respond to a small number of Requests for Admission ("RFAs"). *See* Minute Entry, ECF 261. Intuitive argues that permitting SIS to proffer evidence post-dating November 2022 outside of its limited supplemental production would violate both Federal Rule of Civil Procedure 26 and principles of fairness.

Intuitive repeatedly argues that it is prejudiced by not being able to present evidence of what happened in the real world since the close of fact discovery in November 2022 because the events of the post-November 2022 period serve to undercut SIS's damages calculations in the "but for" world. The Court previously resolved this issue. The limited authority presented by Intuitive does not establish that the factual events taking place since the close of fact discovery should bear on either liability or damages calculations in antitrust cases. The Court permitted limited further discovery for the sole purpose of establishing that SIS did not compete in the market following the close of fact discovery. Even with this backdrop, SIS responded to Intuitive's motion by stating its non-opposition to the limitation so long as the Court added four proposed conditions. The Court accordingly **GRANTS** Intuitive's motion in limine #4 to prohibit SIS's witnesses and lawyers from offering any evidence or argument about the time period following November 10, 2022, other than SIS's recently produced financial records and RFA responses. The Court imposes the following additional conditions:

(1) the prohibition against offering any evidence or argument about what happened after November 2022 outside of the limited information that SIS produced in response to the Court's order applies with equal force to Intuitive, along with its witnesses and lawyers;

(2) SIS's damages expert's updated Schedules appended to his expert report based upon financial data produced by the parties after the close of discovery are not subject to the prohibition against offering any evidence or argument about what the "but for" world would look like after November 2022;

(3) SIS's damages expert is not prohibited from testifying regarding SIS's lost profits in the "but-for" world corresponding to the period after November 2022 through 2026; and

(4) information available after November 10, 2022, which is disclosed or covered in the parties' expert reports and which the parties had a full opportunity to explore through the subsequent expert deposition process are not subject to the prohibition against offering any evidence or argument about what happened after November 2022.

IT IS SO ORDERED.

Dated: December 11, 2024

ARACELI MARTÍNEZ-OLGUÍN
United States District Judge

United States District Court
Northern District of California